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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/544,090	05/15/2006	Xina Nair	PC23207A	7765

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PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
GROTON, CT 06340

EXAMINER	
NATHAN, SHYAM	
ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
10/16/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

~IPGSGro@pfizer.com

Office Action Summary	Application No.	Applicant(s)	
	10/544,090	NAIR, XINA	
	Examiner	Art Unit	
	SHYAM NATHAN	4161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 11-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 11-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 July 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/29/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-9 and 11-19 are currently pending and are the subject of this Office Action.

This is the first Office Action based on the merits of the claims.

Priority

The earliest effective U.S. filing date afforded the instantly claimed invention is 01/22/2004, the filing date of application PCT/IB04/00240.

Claim Objections

Claim 9 (part b) is objected to because of the following informalities: dimethyl 'isorbide' should read isosorbide. Appropriate correction is required.

Claim Rejections - 35 USC § 112 & 101

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 11-19 provides for the use of a formulation according to instant claims 1-9, but, since the claims does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 11-19 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 2-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the limitation "the formulation according to claim 2" in line 1. There is insufficient antecedent basis for this limitation in the claim because a claim cannot depend on itself. Claims 3, 4, and 8 are rejected on the same basis.

Note: Examiner has interpreted claims 2-4 and 8 to depend from claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biedermann et al. (US Patent No. 5,980,921; Issued Nov.9,1999) and Hu (US patent No. 6,132,740; Issued Oct.17,2000).

Instant claim 1-8 are drawn to a pharmaceutical formulation for topically administering a skin-lightening agent, the formulation comprising a skin-lightening agent which said skin lightening agent is a 4-substituted resorcinol which is in admixture with a pharmaceutically acceptable carrier, the carrier comprising a co-solvent and at least one hydroxyl compound selected from the group consisting of glycols, lower alkanols and water.

Biedermann et al. teaches of topical compositions for regulating the oily and/or shiny appearance of mammalian skin, which comprises water as a preferred solvent and propylene glycol and/or ethanol (which is a lower alkanol) as suitable solvents found in 80-99.99% of the composition. (Abstract and column 5, lines 4-16). The composition of Biedermann et al. also comprises slow evaporating glycols such as propylene glycol and hexylene glycol, as well as the preferred solvent dimethyl isosorbide(which is a dianhydrohexitol analog), all of which can be individually present from about 0.5% to 30% in the composition (Abstract and column 10, lines 6-25). Biedermann et al. also teaches the use of Skin Lightening Agents (Abstract and column

16, lines 1-15) in the topical composition but does not specifically mention 4-substituted resorcinols, such as 4-cyclohexyl resorcinol or 4-cylcopentyl resorcinol.

Hu teaches of an invention that relates to the use of 4-cycloalkyl resorcinols, preferably 4-cyclohexyl resorcinol or 4-cylcopentyl resorcinol, that could be used as a topical pharmaceutical composition for lightening skin or reducing the pigmentation of skin in a human. (Abstract and column 3, lines 43-50)

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to have added either 4-cyclohexyl resorcinol or 4-cylcopentyl resorcinol to the composition of Biedermann et al. because Biedermann et al. specifically states that suitable skin lightening agents including those known in the art can be used in the composition of Biederman et al. (Abstract and column 16, lines 7-8) and 4-cyclohexyl resorcinol or 4-cylcopentyl resorcinol as taught by Hu are skin lightening agents.

Instant claim 9 is drawn to, a pharmaceutical formulation for topically administering a skin-lightening agent in which:

a) the skin lightening agent is 4-cyclopentyl resorcinol which is in admixture with a carrier,

b) said carrier is comprised of

a. about 15% (vol/vol) of dimethyl isorbide,

b. about 5% (vol/vol) of hexylene glycol,

c. about 40% (vol/vol) of propylene glycol and,

d. about 35% (vol/vol) of ethanol.

Biedermann et al. teaches of topical compositions for regulating the oily and/or shiny appearance of mammalian skin, which comprises water as a preferred solvent and propylene glycol and/or ethanol as suitable solvents found in 80-99.99% of the composition. (Abstract and column 5, lines 4-16). The composition of Biedermann et al. also comprises slow evaporating glycols such as propylene glycol and hexylene glycol, as well as the preferred solvent dimethyl isosorbide, all of which can be present from about 0.5% to 30% in the composition (Abstract and column 10, lines 6-25).Biedermann et al. also teaches the use of Skin Lightening Agents (Abstract and column 16, lines 1-15) in the topical composition but does not specifically mention 4-substituted resorcinols, such as 4-cyclohexyl resorcinol or 4-cylcopentyl resorcinol.

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It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to have added either 4-cyclohexyl resorcinol or 4-cylcopentyl resorcinol to the composition of Biedermann et al. because Biedermann et al. specifically states that suitable skin lightening agents including those known in the art

can be used in the composition of Biederman et al. (Abstract and column 16, lines 7-8) and 4-cyclohexyl resorcinol or 4-cylcopentyl resorcinol as taught by Hu are skin lightening agents.

Furthermore, the percents (vol/vol) of the compounds in claim 9, can be optimized through routine experimentation to obtain preferable amounts of dimethyl isorbide, hexylene glycol, propylene glycol and ethanol in the composition.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHYAM NATHAN whose telephone number is (571)270-5753. The examiner can normally be reached on Mon-Thurs 8:30a.m. - 5:00p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SN

/Ashwin Mehta/
Primary Examiner, Technology Center 1600